UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Guidant Corp. Implantable Defibrillators Products Liability Litigation	MDL No. 05-1708 (DWF/AJB)
This Document Relates to:	
Peter Wislocki, as trustee of the Spouse and next of kin of Louis Wislocki, decedent, Plaintiff, v. Guidant Corporation and Guidant Sales Corporation Defendants;	Civil No. 05-2957 (DWF/AJB) **MEMORANDUM OPINION AND ORDER**
and	
Patricia Machalowski, individually and as Trustee for the next of kin of John Machalowski, Plaintiff, v. Guidant Corporation; Cardiac Pacemakers, Inc.; and Guidant Sales Corporation Defendants.	Civil No. 05-2958 (DWF/AJB)

Carole Bosch, Esq., Mark E. Burton, Jr., Esq., and Rachel Abrams, Esq., Hersh & Hersh; and Joseph M. Crosby, Esq., Crosby Law Firm, counsel for Plaintiff Peter Wislocki.

Gale D. Pearson, Esq., Matthew J. Schumacher, Esq., and Stephen J. Randall, Esq., Pearson, Randall & Schumacher, PA; Stephen A. Sheller, Esq., and Susan J. Herczeg, Esq., Sheller, Ludwig & Badey; and Martha K. Wivell, Esq., counsel for Plaintiff Patricia Machalowski.

Timothy A. Pratt, Esq., and Deborah A. Moeller, Esq., Shook Hardy & Bacon LLP; and Joseph M. Price, Esq., Faegre & Benson LLP, counsel for Defendants.

The above-entitled matters came before the Court on March 8, 2006, pursuant to Motions to Remand brought by Plaintiffs Peter Wislocki and Patricia Machalowski. Consistent with the Court's Order dated March 14, 2006, the Court grants the Plaintiffs' Motions to Remand.

Background

Plaintiff Patricia Machalowski, individually and as trustee for the next of kin of John Machalowski, filed suit against Guidant Corporation, Cardiac Pacemakers, Inc., and Guidant Sales Corporation (collectively, "Guidant") in Hennepin County District Court on December 14, 2005. Plaintiff Machalowski's Complaint alleges eight counts related to the alleged failure of an implantable cardiovirtual defibrillator, manufactured by Guidant, that was implanted into Patricia Machalowski's husband, John Machalowski: (1) strict products liability; (2) negligence; (3) breach of implied warranties; (4) breach of express warranty; (5) fraudulent concealment; (6) consumer fraud; (7) unlawful trade practices; and (8) wrongful death. Guidant removed the case on December 22, 2005, pursuant to 28 U.S.C. § 1442(a).

Plaintiff Peter Wislocki, as trustee for the spouse and next of kin of Louis Wislocki, decedent, filed suit against Guidant in Ramsey County District Court on December 5, 2005. Plaintiffs are Indiana residents. Plaintiff Wislocki's suit alleges that the automatic implantable cardioverter defibrillator manufactured by Guidant and implanted into Louis Wislocki failed, causing Louis Wislocki's death. Plaintiff Wislocki's suit alleges the following counts: (1) strict liability – failure to warn; (2) strict liability – defective design; (3) negligence; (4) breach of implied warranties; (5) breach of express warranty; (6) fraud; (7) fraud by concealment; (8) negligent misrepresentation; (9) violations of the Minnesota Deceptive Trade Practices Act, Minn. Stat. § 325D.44; (10) violations of the Minnesota False Statement in Advertisement Act, Minn. Stat. § 325F.67; and (11) violations of the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F.69. Guidant removed Plaintiff Wislocki's suit on December 22, 2005, pursuant to 28 U.S.C. § 1442(a).

Plaintiffs Machalowski and Wislocki moved to have their cases remanded. Both Plaintiffs assert that no federal subject matter jurisdiction exists to support removal. Guidant opposes Plaintiffs' motions for remand.

Discussion

The party seeking removal and opposing remand bears the burden of establishing federal subject matter jurisdiction. *In re Business Men's Assur. Co. of Amer.*, 992 F.2d 181, 183 (8th Cir. 1993). Generally, a state court action may only be removed if a

federal district court would have original jurisdiction to hear the case. 28 U.S.C. § 1441(a).

Here, Guidant asserts that removal is proper pursuant to 28 U.S.C. § 1442(a)(1). Section 1442(a)(1) permits removal by the following:

> The United States or any agency thereof or any officer (or any person acting under that officer) of the United States or of any agency thereof, sued in an official and individual capacity for any act under color of such office or on account of any right, title or authority claimed under any Act of Congress for the apprehension or punishment of criminals or the collection of the revenue.

28 U.S.C. § 1442(a)(1). Section 1442(a) requires that a defendant: "(1) act under the direction of a federal officer; (2) show a nexus or 'causal connection' between the alleged conduct and the official authority; (3) have a colorable federal defense; and (4) be a 'person' within the meaning of the statute." *Watson v. Philip Morris Companies, Inc.*, 420 F.3d 852, 855 (8th Cir. 2005).

Guidant contends that in designing, manufacturing, marketing, and distributing the medical devices at issue in these cases, it acted pursuant to rigorous federal regulations and under the continuous supervision and direction of the Federal Food and Drug Administration ("FDA"). Guidant points to the comprehensive pre- and post-approval authority that the FDA wields over Guidant's devices to ensure that the devices are safe and effective. Specifically, Guidant outlines the detailed pre-market approval ("PMA") application process with which Guidant must comply to bring its "Class III" medical devices to market. This application process requires Guidant to provide to the FDA

reports regarding the safety and efficacy investigations performed on Guidant's devices, statements regarding the components and operation of the devices, descriptions of manufacturing and processing controls, information about compliance with performance standards, samples of the devices, and labeling information. 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20. The FDA continues its oversight after a PMA application has been approved. The FDA may impose additional testing, labeling, and distribution requirements even after granting PMA approval. 21 C.F.R. § 814.44; 21 C.F.R. § 814.82(a). The FDA may also revoke its approval if the device manufacturer fails to comply with any post-approval requirements. 21 C.F.R. § 814.82(c).

The FDA also has authority to issue recall orders if it finds that "there is a reasonable probability that [the device] . . . would cause serious, adverse health consequences or death." 21 C.F.R. § 810.10. In fact, the FDA classified recent Guidant physician communications regarding the devices at issue here as a "Class I recall," subjecting Guidant's devices to additional FDA oversight and control.

Guidant contends that because it acted within the bounds of this FDA regulation and oversight, it acted under the direction of the "United States or an[] agency thereof" in producing the devices in question, and that it continues to act under color of federal office in attempting to take corrective action to minimize the risk of additional device failures. 28 U.S.C. § 1442(a)(1). In other words, Guidant contends that it acted under the direction of the FDA because it submitted a PMA application and later recalled the

defibrillators that are at issue in this litigation. It is on these bases that Guidant asserts that federal jurisdiction exists.

In support of its position, Guidant points to the Eighth Circuit Court of Appeals' decision in *Watson v. Philip Morris Companies, Inc.*, 420 F.3d 852 (8th Cir. 2005). In *Watson*, the Eighth Circuit held that consumer litigation brought against tobacco companies was properly removed to federal court pursuant to 28 U.S.C. § 1442(a). The plaintiff-consumers filed suit in Arkansas state court, alleging that the cigarette manufacturer deceptively marketed its cigarettes as "light" or "lowered tar and nicotine" in violation of an Arkansas consumer protection statute. *Id*. at 854. The defendant-cigarette manufacturer removed the action pursuant to § 1442(a)(1). *Id*. The *Watson* court held that the question of whether a defendant was "acting under" the direction of a federal officer depended on the detail and specificity of the federal direction of the defendant's activities and the government's exercise of control over the defendant. *Id*. at 856-57. The court noted that "[m]ere participation in a regulated industry is insufficient to support removal unless the challenged conduct is 'closely linked to detailed and specific regulations.'" *Id*. at 857 (quoting *Virden v. Altria Group, Inc.*, 304 F. Supp. 2d 832, 844 (N.D. W. Va. 2004) (citations omitted)).

In analyzing whether the defendant in *Watson* was acting under the direction of a federal officer, the court noted that the FTC exercised "comprehensive, detailed regulation" and performed ongoing monitoring of the cigarette industry, including specific testing and disclosure of tar and nicotine ratings in advertising. *Id*. at 858. In

fact, the FTC itself conducted the entire testing process of cigarettes for twenty years and afterward required the cigarette manufacturers to conduct the testing according to precise FTC specifications. *Id*. Moreover, the FTC conducted ongoing monitoring of cigarette ads and occasionally brought claims against manufacturers for deceptive advertising. *Id*. The court noted that the record evidenced "an unusually high level of governmental participation and control." *Id*. at 860.

Here, the level of FDA participation and control in bringing the medical devices to market is much less extensive. At the heart of Plaintiffs' complaints are the allegations that Guidant designed and manufactured defective defibrillators, and then failed to remove them from the market after the alleged defects were discovered. On the record before the Court, the FDA did not exercise control over Guidant's design, manufacture, or sale of the defibrillators at issue. The FDA required Guidant to submit information regarding the safety and efficacy of its products, but it did not control the manner in which Guidant created the devices. In addition, there is no link between the FDA's broad regulation of medical devices to the acts challenged in the Plaintiffs' complaints. *See Watson*, 420 F.3d at 861. Specifically, Guidant does not contend that the FDA directed the design, manufacture, or marketing of the defibrillators at issue in a manner that gave rise to the defects and deception alleged in Plaintiffs' complaints. *See Parks v. Guidant Corp*., 402 F. Supp. 2d 964, 971 (N. D. Ind. 2005).[1]

[1] In *Parks*, the Federal District Court for the Northern District of Indiana held that

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Moreover, Guidant's position would allow for federal jurisdiction over virtually any participant in a regulated industry. As the Federal District Court for the Northern District of Indiana aptly noted,

> Were the Court to find this case sufficient to invoke the federal officer removal statute, then there would be little to stop every medical device manufacturer – indeed, every drug manufacturer – sued in state court, and who cannot avail itself of diversity jurisdiction, from removing any garden-variety, products liability case to federal court. This would lead to an unprecedented expansion of federal jurisdiction.

Id. at 968. Guidant has not demonstrated that it acted under the direction of a federal officer, nor has it demonstrated a causal connection between the alleged defects and deception and the FDA's regulatory authority. As such, no federal jurisdiction exists to support removal.

In conclusion, the Court notes that it does not intend for this remand order to compromise, in any way, the Court's attempt to facilitate the coordination of discovery and trials between the state court cases and the MDL. The Court will continue its efforts to serve the interests of justice and the parties by coordinating pretrial matters to effectuate a meaningful and prompt resolution of all of the cases — state and federal.

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no federal officer removal jurisdiction existed in a case involving the alleged malfunction of a Guidant defibrillator. The court found that Guidant did not act under the direction of the FDA in designing, manufacturing, or selling the medical device at issue, and that there was no link between the FDA regulation and involvement with the alleged malfunctions of the defibrillator. *Parks*, 402 F. Supp. 2d at 970.

ORDER

1. Plaintiff Peter Wislocki's Motion to Remand (Civil No. 05-2957 (DWF/AJB), Doc. No. 9) is **GRANTED**.

2. Plaintiff Patricia Machalowski's Motion to Remand (Civil No. 05-2958 (DWF/AJB), Doc. No. 7) is **GRANTED**.

Dated: April 26, 2006

s/Donovan W. Frank
DONOVAN W. FRANK
Judge of United States District Court